NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK A/S, Plaintiff, v. SANOFI-AVENTIS U.S. LLC, et al. Defendants.	CIVIL ACTION NO. 07-3206 (MLC) **MEMORANDUM OPINION**

COOPER, District Judge

Plaintiff, Novo Nordisk A/S ("Novo") commenced this action against defendants, Sanofi-Aventis U.S. LLC ("Sanofi U.S."), Sanofi-Aventis ("Sanofi France"), and Sanofi-Aventis Deutschland GmbH ("Sanofi Germany") alleging, inter alia, that they infringed one or more claims of its United States Patent No. 7,241,278 (the "'278 patent") by importing, selling, or offering to sell their SoloStar product in the United States. (See dkt. entry no. 59, Amend. Compl.) Sanofi U.S. and Sanofi Germany separately filed answers to Novo's amended complaint, which include counterclaims against Novo seeking, inter alia, a declaration that (1) they are immune from Novo's claims in this action, (2) Sanofi U.S. has not infringed the '278 patent, (3) the '278 patent is invalid, (4) the '278 patent is unenforceable because Novo has improperly used it to interfere with competition and extend its monopoly beyond the scope of the patent, and (5) the '278 patent is unenforceable because Novo engaged in inequitable conduct. (Dkt. entry no. 87,

Sanofi U.S.'s Counterclaims, Ans., & Aff. Defs; dkt. entry no. 106, Sanofi Germany's Counterclaims, Ans., & Aff. Defs.) Sanofi France, however, moves to dismiss the amended complaint insofar as asserted against it for lack of personal jurisdiction pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(2). (Dkt. entry no. 88.)

Novo moves to preliminarily enjoin Sanofi U.S. and Sanofi France "from making, using, selling, offering to sell, and/or importing SoloStar in the United States". (Dkt. entry no. 20; see dkt. entry nos. 7-16.) Sanofi U.S. and Sanofi Germany oppose Novo's motion for a preliminary injunction. (Dkt. entry no. 152.)[1] The Court has considered the papers submitted by the parties and heard oral argument on January 25, 2008. (See dkt. entry no. 194.) The Court hereby issues its findings of fact and conclusions of law with respect to Novo's motion for a preliminary injunction as required by Rule 52. For the reasons stated herein, the Court will deny that motion.

[1] Sanofi U.S. and Sanofi Germany also moved for judgment on the pleadings as to Novo's willful infringement claims. (Dkt. entry no. 158.) However, this Court will not address either that motion or Sanofi France's motion to dismiss in this memorandum opinion. Those motions will be addressed at a later time.

BACKGROUND AND FACTUAL FINDINGS

I. Overview of the Parties and Their Insulin Injection Devices

A. Novo

Novo is a corporation organized under the laws of Denmark with its principal place of business in Denmark. (Novo Br., at 4.) Novo's business focuses primarily on developing products to assist persons suffering from diabetes, a disease characterized by persistently high blood sugar levels. (See id. at 4-5.) Most diabetes sufferers use genetically altered insulin products called insulin analogs. (Id. at 5.) Insulin analogs must be taken in precise doses at regular intervals each day, and thus, diabetes sufferers are often reluctant to try a different insulin analog or form of treatment. (Id. at 5-6.) In 2006, Novo launched a new long-acting insulin analog called Levemir. (Id. at 2.)

Insulin analogs were initially administered using syringes. (Id. at 6.) However, in 1985, Novo introduced the first insulin injection pen, the NovoPen. (Id.) Insulin injection pens have a needle where an ink pen would have its tip, and a push button at the opposite end. (Id. at 6.) With a pen, the user does not have to draw insulin from a separate vial, but instead, rotates a knob at one end of the pen to set the correct dosage amount. (Id.) "Nonetheless, while more insulin is now administered by injection pens than by syringes in many parts of the world, sales

of injection pens in the U.S. have risen much more slowly." (Id. at 7.)

Novo has developed more advanced insulin pens since it first introduced the NovoPen in 1985, including pens that are disposable, have a 3-milliliter insulin cartridge, are designed for persons with poor eyesight or reduced dexterity, and have a built-in blood glucose monitor. (Id. at 8.) More recently, Novo developed its best-selling insulin injection pen, the FlexPen. (Id. at 2.)

The FlexPen is a commercial embodiment of the '278 patent, which was issued to Novo on July 10, 2007. The '278 patent claims an insulin injection pen that, inter alia, requires less force to inject the insulin medication and prevents the user from dialing up a dose that exceeds the amount of insulin remaining in the pen. (See id. at 9-11.) Novo's insulin analog Levemir is available in the FlexPen in various countries. (Id. at 2.) However, Novo acknowledged at oral argument that it is not currently marketing its FlexPen in the United States and it has not present plans to do so.

B. Sanofi U.S. and Sanofi Germany

Sanofi U.S. is a Delaware limited liability company with its principal place of business in New Jersey. (Dkt. entry no. 87, Sanofi U.S.'s Counterclaims, Ans., & Aff. Defs., at 41.) Sanofi Germany is a corporation organized under the laws of Germany with

its principal place of business in Germany. (Dkt. entry no. 106, Sanofi Germany's Counterclaims, Ans., & Aff. Defs., at 42.)[2] "Sanofi is part of an international pharmaceutical organization that offers a wide array of innovative cardiovascular, oncology, and other products". (Sanofi Br., at 2.) With respect to those with diabetes, Sanofi introduced its long-acting insulin analog, Lantus, in the United States in January of 2001. (Id.) Lantus is the world's leading long-acting insulin analog. (Id.). It was initially available only in vials for use with syringes, but Sanofi began offering it in a reusable insulin delivery device called OptiClik in January of 2005. (Id.) Thereafter, in 2007, Sanofi introduced SoloStar, a disposable Lantus delivery device, in the United States. (Id.) Novo alleges that SoloStar infringes claims 1 and 7-26 of its '278 patent. (Novo Br., at 11.)

II. The '278 Patent

The '278 patent discloses "[a]n injection device for injection of set doses of medicine from a cartridge, in which syringe a dose is set by screwing a nut up along a threaded piston rod, whereby a dose setting drum . . ., and an injection button, which is elevated over the end of the syringe, are moved axially a distance which is larger than the axial movement of the

[2] Because Sanofi U.S. and Sanofi Germany jointly oppose Novo's motion for a preliminary injunction, we will refer to them collectively as "Sanofi" for the remainder of this opinion.

nut." (Dkt. entry no. 9, Began Aff., Ex. A, '278 patent, at Abstract.) It is composed of 28 claims, but only claims 1, 8, 12, 16, 22 and 25 are independent. (See id. at cols. 7-10.) Further, claims 1 and 7-26 are the only claims at issue here.

According to Novo:

> [c]laims 1, 8-13, and 22-24 are principally concerned with a clutch mechanism that releasably couples the does dial sleeve and the drive sleeve, such that (1) during the dose setting operation, the dose dial sleeve and the drive sleeve are coupled by the clutch so that they rotate together; but (ii) during injection, the dose dial sleeve is decoupled from the drive sleeve by the clutch, allowing the dose dial sleeve to rotate freely while the drive sleeve moves down without rotating at all.

(Novo Br., at 20.) For example, claim 1 describes:

> 1. A drug delivery device comprising:
> a piston rod having at least one threaded portion;
> a dose dial sleeve threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale;
> a drive sleeve for driving the piston rod; and
> a clutch, which is comprised of one or more components that releasably couples the dose dial sleeve and the drive sleeve; and wherein
> (i) during the dose setting operation the dose dial sleeve and the drive sleeve are coupled by the clutch so that they rotate together; and
> (ii) during injecting of medication from the device, the dose dial sleeve is decoupled from the drive sleeve and so that it rotates back to an original pre-dose setting position upon completion of the injection but the drive sleeve does not rotate during injecting of medication but instead moves in a longitudinal direction toward an injecting end of the device.

(Dkt. entry no. 9, Began Aff., Ex. A, '278 patent, col. 7, lines 18-40 (numerical references to portions of diagrams omitted).)

Novo asserts that claims 7, 15-21, and 25-26 also describe a clutch mechanism, and, in addition, describe a mechanical advantage created by requiring the drive sleeve to move a greater distance than the piston rod during injection. (Novo Br., at 24.) Claim 25, for example, states:

> A drug delivery device comprising:
> a piston rod;
> a dose dial threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale; a drive sleeve for transmitting a force that is received at one end of the device to drive the piston rod; and
> wherein the dose dial and the drive sleeve are releasably coupled so that when the device is in a dose setting mode, the dose dial and drive sleeve rotate together and allow a predetermined dose to be set, and during the injection of the predetermined dose the dose dial and the drive sleeve are decoupled and the dose dial rotates with respect to the drive sleeve and rotates to a zero position upon completion of the injection and the drive sleeve moves axially toward an injecting end of the device and wherein the drive sleeve moves a distance that is greater than a distance that is moved by the piston rod during the injecting of the predetermined dose.

(Dkt. entry no. 9, Began Aff., Ex. A, '278 patent, col. 10, lines 20-42.) Lastly, Novo asserts that claims 14 and 18 describe both a clutch mechanism and a "dose limiter" or "end-of-content" function, which prevents the user from dialing up a dose that exceeds the amount remaining in the pen. (Novo Br., at 24; see

dkt. entry no. 9, Began Aff., Ex. A, '278 patent, col. 8, lines 65-67 & col. 9, lines 1-3 (noting that the device comprises "a dose limiter that prevents a dose from being set that is larger than the contents remaining in the device"); id., col. 9, lines 31-35 (noting that the device comprises "a dose setting limiter that prevents a dose that is larger than that remaining in the device from being set").)

III. The DCA Patent Application

DCA Design International Ltd. ("DCA") filed patent application WO 2004/078239 A1 ("DCA Application") with the European Patent Office on March 3, 2003. (Dkt. entry no. 9, Began Aff., Ex. B, WTO DCA App.) DCA filed the United States counterpart to the DCA Application with the United States Patent and Trademark Office ("PTO") on March 3, 2004. (Id., Ex. C, PTO DCA App.) In general, the DCA Application discloses a

> [d]rive mechanism for use in a drug delivery device comprising: a housing having a helical thread, preferably an internal helical thread; a dose dial sleeve having a helical thread engaged with the helical thread of the said housing; a drive sleeve releasably connected to the said dose dial sleeve; and a clutch means located between the dose dial sleeve and the drive sleeve[.]

(Id. at Abstract.) Thus, it encompasses devices substantially similar to those disclosed in the '278 patent.

Novo filed its first priority patent application in Denmark on June 16, 2000, and filed its application for what became the '278 patent with the PTO on September 22, 2003. (Id., Ex. A,

'278 Patent; Novo Reply Br., at 4.) The stated inventor of the '278 patent, Claus Schmidt Møller ("Møller"), testified that he first saw the DCA Application sometime in 2004 and it "exactly described what was the function of NovoPen4", an embodiment of the '278 patent. (Dkt. entry no. 168, Fishman Decl., Ex. 1, 10-24-07 Møller Dep., at 123-24.) Accordingly, he told Novo that he believed the DCA Application and the SoloStar device, which he considered to be a commercial embodiment of the DCA Application, infringed the '278 patent. (Id. at 124-25.)

After Novo reviewed the DCA Application, it had its patent prosecution lawyer copy claims from the DCA Application and insert them into the pending '278 patent application. (Novo Reply Br., at 5-6.) A Novo representative explained that Novo did not inform the PTO in writing that it copied claims from the DCA Application, but the examiner "was well aware of it" from an interview it conducted with Novo. (Dkt. entry no. 147-148, Antonian Decl., Ex. V, Excerpt from 10-18-07 Began Dep., at 215.) Novo believes that (1) DCA is contractually obligated to assign to Sanofi any patents issued to DCA that relate to a disposable insulin injection pen, and (2) the DCA Application was meant to "cover" SoloStar. (Novo Reply Br., at 4-5.) Sanofi contends, however, that "the DCA Application does not describe the SoloStar device. Instead, the DCA Application discloses several different embodiments, and only one embodiment is partly present in portions of the SoloStar device." (Sanofi Br., at 45.)

CONCLUSIONS OF LAW

Novo argues, inter alia, that Sanofi should be preliminarily enjoined from infringing its '278 patent because (1) there is a strong likelihood that it will prevail on the merits, (2) it is entitled to a presumption of irreparable harm and there are several factors that establish irreparable harm, (3) the balance of the hardships favors granting the injunction, and (4) the public interest of protecting patent rights supports granting the injunction. (See Novo Br., at 1-3.) In contrast, Sanofi argues, inter alia, that (1) it is immune from any actions brought in connection with the '278 patent pursuant to a 2001 license agreement,[3] (2) it has raised substantial questions about the validity of the '278 patent, (3) when properly construed, the '278 patent's claims are limited to a device with direct gearing and a non-rotatable piston rod, and SoloStar does not include these elements, and (4) the '278 patent is unenforceable due to Novo's inequitable conduct. (Sanofi Br., at 1-2.) The findings and conclusions set forth in this opinion are preliminary only, and based upon the state of the record at this stage in the litigation. See Fed.R.Civ.P. 65(a). The parties have preserved

[3] The referenced license agreement is governed by German law. (Sanofi Br., at 4.) Sanofi has brought an action in the District Court of Düsseldorf seeking a judgment declaring that it is immune from this action pursuant to the 2001 license agreement. (Id.) Thus, this Court will not address the immunity issue, but will await the decision of the Düsseldorf court.

all rights to present their disputes to a fact-finder for eventual adjudication on the merits.

I. Legal Standards Governing Preliminary Injunctions in Patent Infringement Actions

The Court, in its discretion, may grant a preliminary injunction "to prevent the violation of any right secured by patent." 35 U.S.C. § 283; see Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997). Injunctive relief is a "drastic and extraordinary remedy", which should be granted only in limited circumstances. Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd., 357 F.4d 1319, 1324 (Fed. Cir. 2004). To obtain such interim relief, a movant must demonstrate (1) a reasonable likelihood of success on the merits, (2) irreparable harm if the injunction is not granted, (3) that the balance of hardships favors granting the preliminary relief, and (4) that granting the preliminary relief is in the public interest. PHG Tech., LLC v. St. John Cos., Inc., 469 F.3d 1361, 1365 (Fed. Cir. 2006); Pfizer, Inc. v. Teva Pharm. USA, Inc., 429 F.3d 1364, 1372 (Fed. Cir. 2005); Genentech, Inc., 108 F.3d at 1364. "[A] movant cannot be granted a preliminary injunction unless it established both of the first two factors, i.e., likelihood of success on the merits and irreparable harm." PHG Tech., LLC, 469 F.3d at 1365.

A. Reasonable Probability of Success on the Merits

In order to demonstrate a likelihood of success on the merits, the patent holder seeking the preliminary injunction must

show that (1) "in light of the presumptions and burdens that will inhere at trial on the merits" infringement will likely be shown, and (2) the infringement claim will withstand challenges to the validity and enforceability of the patent. Genentech, Inc., 108 F.3d at 1364; see Entegris, Inc. v. Pall Corp., Nos. 04-1440, 05-1265, 05-1266, & 06-1374, 2007 U.S. App. LEXIS 13812, at *32 (Fed. Cir. June 13, 2007) (noting that a patent holder seeking a preliminary injunction bears the burden of establishing a likelihood of succeed on the merits with respect to the patent's validity). Thus, the Court cannot issue the preliminary injunction if the opposing party raises a "substantial question" regarding the validity, enforceability, or infringement of the patent. Genentech, Inc., 108 F.3d at 1364; see Entegris, Inc., 2007 U.S. App. LEXIS 13812, at *32 (stating that a preliminary injunction should not issue if the alleged infringer raises a "substantial question" regarding the invalidity of the patent).

1. Infringement

An infringement inquiry is a two-step process. First, the Court must determine the scope and meaning of the patent's claims. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). Construction of a patent's claims is a matter of law for the Court. Markman, 517 U.S. at 372 ("[T]he construction of a patent, including terms of art within its claims, is exclusively within the province of the

Court."). Second, the allegedly infringing product is compared to each claim at issue to determine whether the product contains every limitation contained in each claim or the substantial equivalent of any limitation not literally present. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001); Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991).

There is a "'heavy presumption' that a claim term carries its ordinary and customary meaning." CCS Fitness Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). The ordinary and customary meaning of a claim term is the meaning a "person of ordinary skill in the art in question" would give to such term on the effective filing date of the patent application. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). Such a person is deemed to interpret the claim term in the context of the entire patent, including the specification. Id. A claim term should generally be given its ordinary meaning unless the patentees "clearly set forth a definition of the disputed claim term in either the specification or prosecution history." CCS Fitness Inc., 288 F.3d at 1366. Thus, words in a claim are generally given their ordinary and customary meaning in the absence of a contrary indication in the patent specification or file history. Wolverine Worldwide, Inc. v. Nike, Inc., 38 F.3d 1192, 1196 (Fed. Cir. 1994).

When interpreting an asserted patent claim, the Court should look first to the intrinsic evidence of record, which includes the patent's claims, the patent's specification, and the complete prosecution history. Markman, 52 F.3d at 979. Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language. Vitronic Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996). In reviewing this intrinsic evidence, the Court considers the context in which a term is used within both the claim at issue and the claims that are not at issue. Phillips, 415 F.3d at 1314. Further, the Court must interpret claim terms in light of the specification. Id. at 1315 (noting that specification is highly relevant to claim construction and usually dispositive).

The Court, in addition to reviewing the specification, should also consider the patent's prosecution history. Id. at 1317; Graham v. John Deere Co., 383 U.S. 1, 33 (1966) ("It is, of course, well settled that an invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office.") The doctrine of "prosecution history estoppel" requires that a patent's claims be interpreted in light of all PTO proceedings that occurred during the patent application process. Festo Corp. v. Shoketsu Kinzoku Co., Ltd., 535 U.S. 722, 733 (2002) (noting that "prosecution history estoppel" ensures that claims are

interpreted in light of those claims that were cancelled or rejected). Accordingly, the prosecution history is useful in claim construction because it demonstrates how the inventor limited the invention during the course of the patent prosecution, and thus, narrowed the scope of the ultimately patented product. Phillips, 415 F.3d at 1317. Nevertheless, because the prosecution history reflects the ongoing negotiations between the inventor and the PTO, it is often less clear and less useful than the specification. Id.

The ordinary meaning of claim language as understood by a person of skill in the art will be readily apparent to a lay judge in some instances, after he or she reviews the intrinsic evidence, and claim construction will involve simply applying the widely accepted meanings of commonly understood words. Id. at 1314. In such circumstances, general purpose dictionaries may be helpful. Id. However, "heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." Id. at 1321.

2. Validity

A patent is presumed to be valid, and each of its claims are presumed valid independent of the validity of other claims. 35 U.S.C. § 282. A party asserting the invalidity of a patent or

one or more of its claims has the burden of establishing such invalidity, which is satisfied only by clear and convincing evidence. Id.; Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 446 (Fed. Cir. 1986). Clear and convincing evidence is evidence that proves in the mind of the trier of fact an abiding conviction that the truth of the factual contentions is highly probable. Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 830 (Fed. Cir. 1991). However, a party opposing a preliminary injunction need only raise a "substantial question" of invalidity. Entegris, Inc., 2007 U.S. App. LEXIS 13812, at *32. The "showing of a substantial question as to invalidity . . . requires less proof than the clear and convincing showing necessary to establish invalidity itself." Id. (omission in original); Abbott Lab. v. Andrx Pharm., Inc., 452 F.3d 1331, 1335 (Fed. Cir. 2006) ("Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial."). Thus, if the alleged infringer asserts an invalidity defense that the patent holder cannot prove "lacks substantial merit," the Court should not issue the preliminary injunction. Entegris, Inc., 2007 U.S. App. LEXIS 13812, at *32; see Genentech, Inc., 108 F.3d at 1364 (noting that the presumption that a patent is valid does not relieve a patentee moving for a preliminary injunction from demonstrating likely success on all disputed issues, even those concerning the patent's validity).

B. Irreparable Injury

The Court should presume that a patent holder will be irreparably harmed if such holder "establishes a strong showing of likely infringement of a valid and enforceable patent." Pfizer, Inc., 429 F.3d at 1381; see Cordis Corp. v. Boston Scientific Corp., 99 Fed.Appx. 928, 933 (Fed. Cir. 2004) ("Once a patentee shows a likelihood of success on the merits, the court's law presumes an irreparable harm.") However, there are exceptions to the general rule that infringement of a valid patent inherently causes irreparable harm, including a finding that (1) future infringement is unlikely, (2) the patent holder has licensed the patent, or (3) the patent holder delayed in bringing the infringement action. Pfizer, Inc., 429 F.3d at 1381; see Cordis Corp., 99 Fed.Appx. at 933-35 (acknowledging that delay in bringing an action, seeking monetary damages, granting licenses, and relative market effects are factors that may be considered by a court when determining whether the defendant has rebutted the presumption of irreparable harm). If a presumption of irreparable harm attaches, the alleged infringer has the burden of producing sufficient evidence establishing that the patent holder would not be irreparably harmed by denial of the preliminary injunction. Pfizer, Inc., 429 F.3d at 1381. The presence of other infringers in the marketplace does not negate irreparable harm. Id.

C. Harm to Nonmoving Party

The Court must balance the hardships to ensure that the injunction would not harm the alleged infringer more than denial of the injunction would harm the patent holder. See id. at 1382. However, "an alleged infringer's loss of market share and customer relationships, without more, does not rise to the level necessary to overcome the loss of exclusivity experienced by a patentowner due to infringing conduct." Id.

D. The Public Interest

The public interest will almost always favor the plaintiff, if both a likelihood of success on the merits and irreparable injury are demonstrated. See Anton/Bauer, Inc. v. PAG, Ltd., 329 F.3d 1343, 1353 (Fed. Cir. 2003) (noting that the court need not address the public interest factor because the first two preliminary injunction factors were not present). Nevertheless, although the public has an interest in upholding the exclusive rights of a patent holder, this interest "cannot control in every case without obliterating the public interest component of the preliminary injunction inquiry." Cordis Corp., 99 Fed.Appx. at 935. Accordingly, the Court must still consider whether any strong public interests weigh against issuing a preliminary injunction in a patent infringement case. See id. at 935-36 (finding that the district court did not err in considering the public's strong interest in having a broad choice of drug-eluting

stents in reaching its determination that a patent holder was not entitled to a preliminary injunction).

II. Legal Standards Applied Here

A. Reasonable Likelihood of Success on the Merits

1. Infringement Analysis

a. Overview of Novo's Construction of the '278 Patent's Claims

Novo's expert, Charles E. Clemens ("Clemens"), contends that the '278 patent describes injection pens containing "a novel means of coupling and de-coupling a dose dial sleeve and drive sleeve, thereby reducing the force required of the patient to complete an injection." (Dkt. entry no. 11, Clemens Aff., at ¶ 16.) With respect to setting an insulin dose, Clemens interprets the '278 patent as stating that (1) a user can rotate a dose setting button located at the top of the dose setting drum (which fits inside the pen-shaped housing) to set the correct dosage, (2) rotation of the dose setting drum causes it to back up and out of the pen's housing, (3) a coupling connects the dose setting drum to a tubular part, and thus, causes the tubular part to rotate in unison with the dose setting drum and also to be lifted upwards, and (4) the tubular part is connected to a nut threaded on the outside of a piston rod, which rotates upward on the piston rod's threads due to the rotation of the tubular part. (Id. at ¶¶ 18, 20, 22.) Thus, when a user turns the dose setting drum, the nut is ultimately rotated up the piston rod, which fits

into the cartridge of medication placed inside the pen housing. (See id. at ¶¶ 18, 23.)

With respect to injection, Clemens asserts that the '278 patent explains that when the user presses the injection button located at the top of the tubular part, the tubular part forces the nut and ultimately the piston rod downward causing the piston rod to push medication out of the cartridge and into the pen housing. (Id. at ¶ 24.) Further, when the injection button is pressed, the coupling part de-couples causing the tubular part to disconnect from the dose setting drum and move downward without rotating. (Id. at ¶ 25.) "With de-coupling, more of the patient's force goes directly to moving the piston rod down. The result is that less force is required of the patient to accomplish the injection." (Id. at ¶ 26.) In addition to this important benefit, Clemens notes that the '278 patent also discloses (1) a dose setting limiter, which prevents the user from setting a dose that exceeds the amount of insulin remaining in the injection pen, and (2) a tubular design that requires the user to push the injection button farther than required with other models, and thus, the user needs to use less force and has the sensation of having pressed "a measurable amount even if he or she only moved the piston down the cartridge a fraction of that distance." (Id.)

Clemens focuses his analysis principally on the '278 patent's claims. He does not rely on the specification. In light of Clemens's analysis, Novo argues that the terms used in the '278 patent's claims, including "dose setting" and "injecting", have clear and unambiguous meanings that do not in any way suggest that these claims should be construed as requiring direct gearing, a gearbox, or a non-rotating piston rod. (See Novo Reply Br., at 11-16.)

b. Overview of Sanofi's Construction of the '278 Patent's Claims in Light of the Specification

Sanofi's expert, Neil Sheehan ("Sheehan"), essentially argues that the '278 patent's claims should be construed in light of the specification. He describes the '278 patent as "directed to a medication delivery device that has a very specific design according to the inventor that was necessitated by the industry change from 1.5 ml [insulin] cartridges to 3 ml medication cartridges." (Dkt. entry no. 146, Sheehan Decl., at ¶ 62.) Sheehan notes that the '278 patent's specification expressly states, inter alia, that its objective is to create a device that combines the advantages of the prior art without the disadvantages, and provides "direct gearing, i.e. a gearing by which more transformations of rotational to linear movement and linear movement to rotational movement are avoided, between the injection button and the piston rod." (Id. at ¶ 64 (quoting '278 patent, col. 2, lines 42-49).) Against this backdrop, Sheehan

asserts that the '278 patent's claims cover devices that must include a direct gearing component, which is located between an injection button and a piston rod and eliminates conversions of rotational movement to linear movement and vice versa. (Id.) Further, Sheehan emphasizes that the '278 patent's only two embodiments include direct gearing, and thus, the patent "does not discuss, disclose or suggest any embodiment of the claimed invention that does not include direct gearing." (Id. at ¶ 65.) The only structure described in the '278 patent that could be characterized as a direct gearing component is the "gearbox" described in the specification. (Id. at ¶ 64 (quoting '278 patent, col. 3, lines 1-18 (stating that the gearbox comprises at least one gear wheel engaging a first and second rack)).)

With respect to dose setting, Sheehan does not dispute that the process is as described by Clemens. However, he contends that direct gearing is necessary to effectuate this process. Specifically, "the dose setting drum is rotated about threads having a 'second pitch' (the distance between threads) that is greater than the 'first pitch' of the threads on the non-rotatable piston rod[, and] . . .the direct gearing structure is the mechanism that must compensate for 'the ratio of said second pitch and said first pitch.'" (Id. at ¶ 66 (quoting portions of '278 patent's specification).) In other words, the "pitch" of the threads on the dose setting drum and the piston rod are

different, and thus, a direct gearing mechanism is needed to compensate for this difference in thread pitch or the device would jam. (See id.)

With respect to injecting a set dose, Sheehan again does not dispute that the process is as described by Clemens. However, he contends that direct gearing is necessary to effectuate the injection process as described in the '278 patent. Specifically, the stated objective in the '278 patent's specification of preventing rotational movement from transforming to linear movement and vice versa can only be achieved if the linear movement of the injection button causes only linear movement of the nut and piston rod. (Id. at ¶ 68.) The specification describes a gearbox as the mechanism that ensures that pressing the injection button moves the piston. (Id. (quoting '278 patent's specification).) Accordingly, Sheehan argues that "a direct gearing component is absolutely necessary to accomplish the objectives stated by the Novo inventor." (Id.)

Sheehan, in addition to asserting that the '278 patent's specification limits the claims to an injection device that includes direct gearing, similarly asserts that the specification limits the claims to an injection device with a non-rotatable piston rod. (Id. at ¶ 69.) Sheehan notes that the only embodiment of the piston rod described in the specification refers to a piston rod that is not rotated. (Id. (quoting '278

patent at col. 3, lines 46-50 ("A threaded piston rod 4 has a not round cross section by which it fits through a central opening in the wall 2 so that the piston rod 4 can be displaced longitudinally through the central opening in the wall 2 but not rotated relative to this wall.")).) Further, Sheehan explains that "if the rod were allowed to rotate, the nut would not reliably thread up the rod during dose setting because the rod would also tend to run when the nut is turned." (Id. at ¶ 70.) Therefore, Sheehan asserts that the '278 patent's claims must describe an injection device with a non-rotatable piston, or the objectives of the dose setting and injection processes could not be fulfilled. (Id. at ¶ 71.)

Sheehan's ultimate conclusion is that in order for the device to function as claimed, each of the '278 patent's claims that are at issue here must include the following two structural elements even if not expressly stated in the claim: (1) a gearbox or direct gearing comprised of at least one gear wheel engaging the first and second rack, and (2) a non-rotating piston rod. (Id. at ¶ 72.)

c. Sanofi's Claim Construction Arguments Raise Substantial Questions Regarding Infringement

There are "twin axioms" regarding the role of a patent's specification in construing the patent's claims. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 904 (Fed. Cir. 2004). "On one hand, claims must be read in view of the

specification of which they are a part. On the other hand, it is improper to read a limitation from the specification into the claims." Id. (internal citations and quotations omitted). Accordingly, the specification may reveal (1) a specific definition for a claim term, or (2) an intentional disclaimer or disavowal of claim scope. Phillips, 415 F.3d at 1316; see Data Encryption Corp. v. Microsoft Corp., No. 06-1603, 2007 U.S. App. LEXIS 21270, *7 (Fed. Cir. Sept. 6, 2007) (concluding that because the specification states that "[a]ll data subject to encryption by operation of the present invention is maintained in an encrypted state in the [kernel memory] buffer pool", the patentee disavowed coverage of systems maintaining data subject to encryption in an unencrypted state in the buffer pool); SafeTcare Mfg., Inc. v. Tele-Made, Inc., 497 F.3d 1262, 1270 (Fed. Cir. 2007) (explaining that the court was not importing limitations from the specification into one of the patent's claims, but instead was using the specification to understand what the patentee had claimed and disclaimed). Thus, this Court has the task of construing the '278 patent in light of the specification, but without unnecessarily importing limitations from the specification into the claims. Liebel-Flarsheim Co., 358 F.3d at 905.

The Federal Circuit, in SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., addressed whether the

common specification of three patents limited the scope of the patents' claims. 242 F.3d 1337, 1340 (Fed. Cir. 2001). There, the plaintiff owned three patents claiming features of balloon dilation catheters containing two passageways or lumens. Id. at 1338-39. The plaintiff claimed that the defendant was infringing each of its three patents. Id. The district court granted summary judgment in favor of the defendant and concluded that it had not infringed the disputed patents. Id.

On appeal, the issue before the Federal Circuit was whether the common specification of the three patents limited the scope of the patents' claims to catheters with coaxial lumens. Id. at 1340.[4] The court explained that if "the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." Id. at 1341. The court then discussed several cases where claims were construed narrowly in light of the specification. Id. at 1341-42.

The Federal Circuit noted that at various points, the patents' common specification indicated that the claimed

[4] The two possible lumen arrangements are: (1) the dual lumen configuration where the two lumens are positioned side-by-side within the catheter; and (2) the coaxial lumen configuration where a guide wire lumen runs inside an inflation lumen (creating an annular shape). Id. at 1339.

invention used coaxial lumens. Id. at 1342. The court also noted that the specification described the disadvantages of certain prior art structures, including catheters with shortened guide wire lumens or dual lumens. Id. at 1342-43. Moreover, the court explained that the "summary of invention" section of the patent described the coaxial configuration as "the present invention", and the court considered this "strong evidence that the claims should not be read to encompass the opposite structure." Id. at 1343; see id. at 1344 (emphasizing that many statements in the specification define "the invention" as having the coaxial configuration, and one statement even notes that the structure containing coaxial lumens applies to "all embodiments of the present invention"). Thus, the court concluded that this was a clear case of "disclaimer of subject matter". Id. at 1344. Therefore, the court held that the district court properly entered summary judgment in favor of the defendant on the issue of literal infringement because the patents disclaim the dual or side-by-side lumen configuration and read only on catheters with coaxial lumens. Id. at 1340, 1345.[5]

The SciMed court essentially reached its determination that the patents' claims were limited to coaxial lumens based on the specification's disclaimer of the side-by-side lumens

[5] The Federal Circuit also agreed with the district court that a reasonable jury could not find that the defendant's accused devices infringed the plaintiff's patents under the doctrine of equivalents. Id. at 1347.

alternative. See Liebel-Flarsheim Co., 358 F.3d at 906. The Federal Circuit has similarly held in many other cases "that the embodiments of the invention set forth in the specification constituted the invention itself, in spite of claim language that could, in the abstract, be interpreted more broadly." Id. at 907 (citing cases). However, in each of those cases, the court gave reasons for the narrow claim construction "beyond the mere fact that the specification disclosed only a single embodiment or a particular structure." Id. at 907-08 (explaining that the patentees in the cases described limited their inventions in the specification by, inter alia, distinguishing prior art, giving limiting definitions, or making clear that the invention was limited to a particular structure). Accordingly, a patent's claims should not be narrowly construed simply because its specification contains one or two narrow preferred embodiments. See id. at 908-09 (concluding that this was not a case where there were applicable reasons for limiting the patent's claims in light of the preferred embodiment); RF Del., Inc. v. Pac. Keystone Tech. Inc., 326 F.3d 1255, 1264 (Fed. Cir. 2003) (finding that district court erred by, inter alia, incorporating the "most preferred embodiment" into a claim); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325 (Fed. Cir. 2003) ("[C]laims are best understood in light of the specification of which they are a part, however, courts must take extreme care when ascertaining the proper scope of the claims,

lest they simultaneously import into the claims limitations that were unintended by the patentee. . . . The danger of improperly importing a limitation is even greater when the purported limitation is based upon a term not appearing in the claim."). However, the Court can assume that a patentee has disclaimed certain claim scope if the specification repeatedly emphasizes certain attributes as important to the invention in distinguishing prior art. See SafeTcare Mfg., Inc., 497 F.3d at 1270 (determining that (1) the written description emphasized that the patented invention's motor applied a pushing force that distinguished it from prior art, and (2) the patent disclaimed motors using pulling forces).

This Court must construe the '278 patent in light of the specification without importing limitations from the specification into the claims. See Liebel-Flarsheim Co., 358 F.3d at 905. As background, the '278 patent's specification explains that problems arose when it became desired that insulin injection pens hold 3 ml of medication rather than only 1.5 ml. (Dkt. entry no. 9, Began Aff., Ex. A, '278 patent, at col. 1, lines 36-54.) These problems eventually led to "a wish for gearing between the injection button and the piston". (Id. at col. 1, lines 55-57.) The specification then describes certain prior art wherein:

> [(1)] a gearing is obtained by the fact that a dose setting element is screwed up along a spindle having a

> thread with a high pitch. When said dose setting element is pressed back in its axial direction the thread will induce a rotation of said dose setting element, which rotation is via a coupling transmitted to a driver nut with a fine pitch which driver nut will force a threaded not rotatable piston rod forward[;] (id., col. 1, lines 61-57)
>
> [(2)] the thread with the high pitch is cut in the outer surface of a dose setting drum and is engaged by a mating thread on the inner side of the cylindrical housing. However, by this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces[; and] (id. at col. 2, lines 2-7)
>
> [(3)] two integrated gear wheels engages [sic] a rack fixed in the housing and a rack inside a plunger, respectively. When the plunger is moved axially in the housing the rack inside this plunger can drive the first gear wheel to make the other integral gear wheel move along the fixed rack in the housing. Thereby the gear wheel is moved in the direction of the plunger movement but a shorter distance than is this plunger and this axial movement of the integrated gear wheels is via a housing encompassing said gear wheels transmitted to a piston rod. . . . A disadvantage of this construction is that the teeth of the racks and gearwheels alternating have to be brought in and out of engagement with each other with the inherent danger of clashing. (Id. at col. 2, lines 10-38.)

In light of the recognized problems with these prior art references, the '278 patent's specification explains that an objective of the present invention is to combine the advantages of the prior art devices without adopting their disadvantages. (Id. at col. 2, lines 42-45.) It further explains that it is an objective of the invention to "provide a device wherein is established a direct gearing, i.e. a gearing by which more transformations of rotational movement to linear movement [and

vice versa] are avoided, between the injection button and the piston rod." (Id. at col. 2, lines 45-49.) Thus, like the specification at issue in SciMed, the specification here criticizes certain prior art types of "gearing" that may be used between the injection button and piston, and expressly states that the invention as a whole is intended to establish a device with "direct gearing". (See generally id. at col. 1, lines 61-67 & col. 2, lines 1-49; see also id. at col. 2, lines 7-8 (stating that a "traditional gearing using mutual engaging gear wheels and racks is preferred").) See 242 F.3d at 1342-43 (emphasizing that the specification at issue (1) indicated that the claimed invention used coaxial lumens in several places, and (2) described the disadvantages of certain prior art structures, including catheters with dual lumens).

The '278 patent's specification explains that its objective of providing a device with direct gearing can be obtained by an injection device comprising (1) a housing wherein a non-rotatable piston rod is threaded with a first pitch, (2) a nut engaging the threading of the piston rod, (3) a dose setting drum that can be screwed outward in the housing along a thread with a second pitch in order to lift an injection button, and (4) a gearbox that "provides a gearing between the axial movements of the injection button and the nut relative to the housing which gearing has a gearing ratio corresponding to the ratio of said second and first

pitch." (Id. at col. 2, lines 50-65.) Further, the specification describes a preferred embodiment wherein the gearing between the injection button and the nut is obtained by a "gearbox". (Id. at col. 2, lines 67-68 & col. 3, line 1.) It then purports to describe "the invention" in further detail with references to diagrams. (Id. at col. 3, lines 29-30.)

In describing "the invention", the patentee states, inter alia, that (1) figure 2 schematically shows a section view of the gearbox, (2) figure 1 shows a sectional view of an injection device "according to the invention", which has a threaded piston rod that can be displaced longitudinally through a central opening in a partitioning wall but cannot rotate relative to such wall, (3) there is a ring shaped coupling element on the gearbox, which allows the gearbox to rotate inside the housing without being displaced, (4) the gearbox has a gear wheel assembly comprised of two integral gear wheels attached to a shaft that "runs perpendicular to the longitudinal axis of the device between two axial connection bars[, which] project from the gear box towards the partition wall and are connected to a nut which adjacent to the wall engages the thread of the piston rod", (5) a tubular dose setting drum engages the outer thread of a tubular element at one end and has a dose setting button at its other end, and (6) there are coupling means between the dose setting drum and a cup shaped element, and rotation of the dose setting

drum via the cup shaped element is transmitted to the gearbox. (Id. at col. 3, lines 31-34, 42-66 & col. 4, lines 11-15, 19-28 (numerical references to portions of diagrams omitted); see id. at col. 3, lines 51-55 & col. 4, lines 4-12 (similarly noting that "[d]ue to the coupling 21, the cup shaped element will follow the rotation of the dose-setting drum 17" and that rotation "is further transmitted to the gearbox 9 through the protrusions 23 on this gearbox engaging the longitudinal recesses 22 in the inner wall of the tubular part 20").)[6] See SciMed Life Sys., Inc., 242 F.3d at 1343 (stating that because the "summary of invention" section of the patent described the coaxial lumen configuration as "the present invention", this was "strong evidence that the claims should not be read to encompass the opposite structure"). Thus, the '278 patent's specification repeatedly refers to a gearbox as a necessary structure in discussing how the patent's objective could be obtained and in describing "the invention" in further detail. See id. at 1344 (emphasizing that many statements in the specification define "the invention" as having the coaxial configuration); but see Karlin Tech., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 773 (stating that the written description had many references to "preferred embodiment" and "the invention", and concluding that

[6] The specification also notes that figures 3 and 4 show a preferred embodiment of the claimed invention that uses only one size gear wheels.

the patentee used both of these terms interchangeably simply to refer to one preferred embodiment). It also refers to a non-rotatable piston in describing "the invention" in further detail. See SciMed Life Sys., Inc., 242 F.3d at 1344.

Sanofi asserts, inter alia, that (1) because Novo's specification characterizes "the invention" as having direct gearing, all possible embodiments of the invention must have such direct gearing, and specifically, a gearbox, (2) the '278 patent's specification describes the dose setting and injection functions in such a way that direct gearing is essential, (3) all embodiments described in the '278 patent refer to a non-rotatable piston rod, and (4) a rotatable piston rod would render the device inoperable. (Sanofi Br., at 30-33.)[7] Sanofi notes that during his deposition Novo's expert, Clemens, was asked, "[i]f the dose setting drum is connected to the tubular part and the tubular part is connected to the nut without a gearbox, and there is different threads, different pitched threads, will that device function?" (Dkt. entry nos. 147-148, Antonian Decl., Ex. R, Excerpt from 10-25-07 Clemens Dep., at 130.) Clemens responded, "I think I understand what you are asking. You would have obviously two threads working against each other in that

[7] Novo describes Sanofi's claim construction as "torture of the English language" and emphasized that "[i]t is a bedrock principle of patent law that a proper claim construction must always begin with, and remain centered on, the language of the claims themselves." (Novo Reply Br., at 10.)

instance. . . . That would jam." (Id.) Moreover, the alleged inventor of the '278 patent, Møller, testified that "there's two embodiments, preferred embodiments, described in the patent. And both of them requires a gearbox." (Dkt. entry no. 168, Fishman Decl., Ex. 1, Excerpt from 10-24-07 Møller Dep., at 126.) He also testified, however, that the specification as a whole does not require use of a gearbox. (Id. at 126-127.) In light of the specification and the above-referenced testimony, Sanofi contends that SoloStar does not infringe the '278 patent because it does not have a gearbox or non-rotatable piston rod, but instead uses threaded connections with different pitches between its components and a rotatable piston rod. (See Sanofi Br., at 10; Novo Reply Br., at 3 (acknowledging that SoloStar using threading instead of a gearbox).)

This Court believes that Sanofi has raised substantial questions regarding whether the specification read as a whole suggests that the very character of the invention requires direct gearing and a non-rotatable piston rod to be part of every embodiment. See Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1370 (Fed. Cir. 2002) (explaining that a court must consider whether a specification "refers to a limitation only as part of less than all possible embodiments" or whether the limitation must be part of every embodiment). Specifically, the Court concludes, after reviewing the specification and the '278

patent's claims, that there are "substantial questions" regarding whether (1) the embodiments of the invention set forth in the specification as "the invention" constitute the invention itself despite claim language that could be interpreted more broadly, (2) the specification expressly disclaims injection pens with rotating piston rods or gearing other than direct gearing, (3) the specification suggests the need to narrowly construe the claims because it distinguishes prior art or clearly expresses an intention to limit the invention's structure, and (4) Novo's amendment of the '278 patent's claims to import language from the DCA Application affects this Court's use of the specification, which was not amended, in construing such claims (i.e., whether the Court should ignore the specification and assume that Novo abandoned the gearbox in favor of the clutch mechanism when it amended its claims to import claims from the DCA Application). See Liebel-Flarsheim Co., 358 F.3d at 906-908.

The Court also has examined the prosecution history and has not found any evidence sufficiently answering these "substantial questions." In fact, the Notice of Allowance issued on April 23, 2007 in connection with the '278 patent explains that the reason for allowance was that the prior art does not disclose or suggest a dose dial sleeve and a drive sleeve or tubular element

> that are releasably coupled together so that these elements rotate together in a dose setting operation to set a dose and decouple from each other in an injection operation allowing the dose dial sleeve to rotate and

> the drive sleeve to move in a longitudinal direction toward the injection end.

(Dkt. entry no. 168, Fishman Decl., Ex. 16, 4-23-07 Not. of Allowance, at "Detailed Action" (distinguishing Burroughs and Steenfeldt-Jensen prior art).) The Notice of Allowance also contains certain examiner's amendments, which were authorized by Novo during a telephone interview held on April 9, 2007. (Id.) The only examiner's amendment to the specification inserted "now U.S. Pat. No. 6,663,602" on the first line. (Id.) Thus, the prosecution history does not shed any light on these substantial questions.[8]

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[8] However, the prosecution history of United States Patent No. 6,663,602 ("'602 patent") does provide some insight. Møller filed application 09/882,536 ("'536 Application") with the PTO on June 14, 2001 (i.e., before he filed the application for what became the '278 patent in the United States). (Dkt. entry no. 147-148, Antonian Decl., Ex. G, Prosecution History for U.S. Patent No. 6,663,602 B2.) The '536 Application claimed an injection device. (Id.) The patent examiner rejected 2 of the 4 claims contained in the '536 Application as being anticipated by an existing patent that disclosed "an invention device having a housing having a piston rod 23 with a thread, a nut 22 engaging the thread, a dose-setting drum 14 (acting together with elements 15, 10), and a gearbox 18." (Id. at 9-27-02 Office Action Summary (Bates Nos. STR0096431-34).) The remaining two claims were objected to as dependent on a rejected claim. (Id.) In response, Møller cancelled the 4 claims and replaced them with 15 new claims. (Id. at 12-6-02 Amend. (Bates Nos. STR0096436-442).) All but one of the amendment's independent claims expressly disclosed an injection device comprising a gearbox. (Id.) Further, the inventor explained in the "remarks" section of the amendment that the invention "uses a gear box to couple axial movement of the injection button to axial movement of the nut, which is in turn coupled to the piston rod to produce axial movement of the rod. . . . . The gear box of the present invention drives the nut axially without necessarily rotating it to expel a dose". (Id.) After a subsequent rejection of one

The Court concludes that Novo has not shown that Sanofi's asserted defense that SoloStar does not infringe the '278 patent because it lacks direct gearing and a non-rotatable piston rod, lacks substantial merit. See Abbott Lab., 452 F.3d at 1335. Thus, we find that granting the preliminary injunction is not appropriate. See Genentech, Inc., 108 F.3d at 1364. Specifically, we find that the substantial questions Sanofi has raised preclude a finding that Novo has a likelihood of success on the merits because it has not sufficiently demonstrated that "in light of the presumptions and burdens that will inhere at trial on the merits" infringement will likely be shown. See id. Nevertheless, the Court notes that its holding should not imply that the record supports a determination that the SoloStar device does not infringe any claim of the '278 patent, or that summary judgment in favor of Novo is not possible on a more fully developed record. See id. at 1335 ("Vulnerability is the issue at the preliminary injunction stage").

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claim and a responsive amendment, the PTO issued a notice of allowance with respect to the '536 Application, which resulted in the '602 patent. (Id. at Not. of Allowance (Bates Nos. STR0096459-63).) The '602 patent was then assigned to Novo. (See id. at Fee Transmittal (Bates No. STR0066464).) The '278 patent states that it is a continuation of the '536 Application "now Pat. No. 6,663,602." (Dkt. entry no. 9, Began Aff., Ex. A, '278 patent.) Thus, it seems that Novo at least contemplated devices with direct gearing when it initially filed the application that later resulted in issuance of the '278 patent.

2. The Validity of the '278 Patent

In light of our conclusion that substantial questions impede our invalidity analysis, and thus, Novo has not demonstrated a reasonable likelihood of success on the merits, it is not necessary for this Court to address the validity of the '278 patent at this time. However, we emphasize that patents are presumed valid and the burden of proof rests with the party asserting an invalidity defense. See 35 U.S.C. § 282; Genentech, Inc., 108 F.3d at 1364 (explaining that a court cannot issue a preliminary injunction if the opposing party raises a "substantial question" regarding either the validity, enforceability, or infringement of the patent).

B. Irreparable Harm, Balance of Hardships, and the Public Interest

As explained above, this Court finds that Novo has not shown a likelihood of success on the merits with respect to infringement. See Genentech, Inc., 108 F.3d at 1364. Accordingly, the Court need not address the remaining preliminary injunction factors. PHG Tech., LLC, 469 F.3d at 1365 ("[A] movant cannot be granted a preliminary injunction unless it established both of the first two factors, i.e., likelihood of success on the merits and irreparable harm.").

CONCLUSION

The Court, for the reasons stated supra, will deny Novo's motion for a preliminary injunction. The Court will issue an appropriate order.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: February 19, 2008